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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/357,704	07/20/1999	NEIL H. BANDER	242/024	9622
26161	7590	12/12/2003	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			NICKOL, GARY B	
		ART UNIT	PAPER NUMBER	25
		1642		
DATE MAILED: 12/12/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/357,704	BANDER, NEIL H.
	<b>Examiner</b>	<b>Art Unit</b>
	Gary B. Nickol Ph.D.	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 09 July 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 69-80,83-94,124-127,129,130 and 132-189 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 69-80,83-94,124-127,129,130 and 132-189 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>23</u> . | 6) <input type="checkbox"/> Other:  |

***Response to Amendment***

The Amendment filed July 7, 2003 (Paper No. 24) in response to the Office Action of January 23, 2003 is acknowledged and has been entered.

Claims 1-68, 81-82, 95-123, 128, 131, are cancelled.

Claims 164-189 were added.

Claims 69-80, 83-94, 124-127, 129-130, and 132-189 are pending and are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

***Election/Restrictions***

The restriction of Claims 160-163 (Paper No. 22) is withdrawn in view of applicant's arguments (Paper No. 24, page 17).

**Rejections Maintained:**

Claims 69-80, 83-94, 124-127, 129-130, and 132-189 are rejected under 35 USC 112, 1<sup>st</sup> paragraph, scope of enablement for the reasons of record in Paper No. 22.

Whereas applicants argue that a patent application is not an application for FDA approval, and human experimentation and data are not required for patentability (*In re Brana*), such arguments are not persuasive because they fail to distinctly address the scope of the claims with regards to *preventive* modalities. As applicants have pointed out (Paper No. 24, page 18), the decision of *In re Brana* dealt with chemical compounds for use as anti-tumor agents with the court deciding that the showing of activity in an animal model was sufficient for patentability. However, evidence that a compound is anti-tumorigenic in an animal model does not make it predictable that the same compound could be used to prevent cancer. The method essentially encompasses a vaccination against prostate cancer, which is highly unpredictable based on the specification as filed. As set forth previously, the essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in advance of clinical cancer and *link* those results with subsequent histological confirmation of the presence or absence of disease. Further, contrary to applicant's arguments (Paper No. 24, page 20), there has been no insistence that applicants supply human data; as testing the drug on *subjects* could include data derived from non-human mammalian subjects such as rats, mice, or rabbits. Thus, applicant's arguments have not been found persuasive and the rejection is maintained.

Claims 68-78, 83-94, 124-127, 129-130, 132-171, 174-189 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record in Paper No. 22, pages 6-7.

Applicants argue (Paper No. 24, page 20) that they have amended the claims to recite antibodies “which bind to an epitope” which is “also recognized by a monoclonal antibody selected from an E99, a J415, a J533 or a J591 monoclonal antibody”. Applicants further note that the Examiner has indicated in telephone interviews that such an amendment would obviate this rejection. This argument has been considered but is not found persuasive. It is noted that there is no record of a telephone interview that indicates the suggested claim language would obviate the rejection. Moreover, whether in telephone interviews or off the record conversations, the Office may suggest certain claim language, however such suggestions cannot supercede the statutes. In this particular case, the suggested claim language of an antibody or antigen binding portion thereof which binds to an epitope of prostate specific membrane antigen which is also recognized by a monoclonal antibody selected from the group consisting of an E99, a J415, a J533, and J591 monoclonal antibody has no clear support in the disclosure as filed. Thus, applicant’s arguments have not been found persuasive and the rejection is maintained.

**New Rejections/Objections:**

***Specification***

The specification is objected to on page 42, line 3 for reciting “nucleotide” since the sentence is in reference to an amino acid sequence.

The specification is objected to on page 43, line 33 for reciting “nucleotide” since the sentence is in reference to an amino acid sequence.

The specification is objected to on page 44, line 33 for reciting "nucleotide" since the sentence is in reference to an amino acid sequence.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 84, 86, 88, 90, 92, 94, 133, 135, 175, 177, 179, 181, 183, and 185 are further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims are broadly interpreted to encompass antigen binding portions that are conjugated, and the specification does not appear to have support for such combinations. For example, Claim 86 is drawn to antibody or antigen binding portion thereof that comprises an antigen binding portion of an amino acid sequence from SEQ ID NO:8 *and* an antigen binding portion of an amino acid sequence from SEQ ID NO:19. However, the specification only supports those antigen binding portions *selected from the group consisting of* SEQ ID NO:8, SEQ ID NO:19, an amino acid sequence of the variable heavy chain produced by the hybridoma having ATCC deposit No. HB-12126, and an amino acid sequence of the variable light chain produced by the hybridoma having ATCC deposit No. HB-12126. Hence, this is a new matter rejection wherein the newly presented subject matter broadens and or deviates from the scope of the invention as originally disclosed in the specification.

Art Unit: 1642

Although, the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP § 714.02 and § 2163.06 (“Applicant should specifically point out the support for any amendments made to the disclosure.”).

No claim is allowed.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

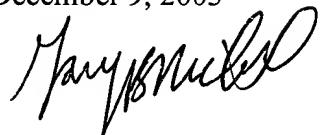
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Art Unit: 1642

Gary B. Nickol, Ph.D.  
Examiner  
Art Unit 1642

GBN

December 9, 2003

A handwritten signature in black ink, appearing to read "Gary B. Nickol".